REMARKS

Claims 45-55 are pending in the instant application. Claims 45, 46 and 48-55 have been rejected. Claim 47 has been objected to. Claims 45 and 47 have been amended. No new matter has been added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Rejection of Claims Under 35 U.S.C. 112, First Paragraph

Claims 45, 46 and 48-55 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The Examiner acknowledges that the specification while being enabling for reducing the viability and growth of melanoma tumors using antisense targeted to human focal adhesion kinase of SEQ ID NO: 18 through ex vivo treatment of animals does not reasonably provide enablement for any antisense targeted to human focal adhesion kinase delivered systemically. The Examiner cites several articles to support the position

concerning the unpredictability of antisense. Applicants respectfully disagree. However, in an earnest effort to advance the prosecution, Applicants have amended claim 45, and its dependent claims, to recite that the invention involves *ex vivo* administration of antisense compounds. Support for these amendments to the claims can be found throughout the specification as filed but in particular at pages 51-56. Accordingly, withdrawal of the rejection is requested in light of these amendments.

II. Rejection of Claims Under 35 U.S.C. 102

Claims 45 and 46 have been rejected under 35 U.S.C. 102(e) as being anticipated by Cance et al. (US Patent 6,015,893). The Examiner suggests that this patent discloses a method where melanoma cells are treated with antisense to focal adhesion kinase, 20 and 24 mer, that target the coding region of focal adhesion kinase, and then injection of these and melanoma cells into mice wherein the viability of the cells and tumor cell invasion properties were inhibited. Applicants respectfully traverse this rejection.

At the outset, Applicants have amended the claims to recite antisense compounds targeted to specific regions other than the

coding region of human focal adhesion kinase of SEQ ID NO: 1. Support for these amendments to the claims can be found at pages 42-43 of the specification as filed.

Cance et al. (US Patent 6,015,893) discloses antisense compounds and their use to inhibit expression of focal adhesion kinase in animals, specifically to reduce cancer growth. Although the patent discloses antisense targeted to the coding region of focal adhesion kinase, no other antisense specific for any other region of human focal adhesion kinase are taught by this reference. In order to anticipate a claim, the cited reference must teach and every limitation of the claims (MPEP 2131). This reference fails to teach the limitations of the claims as amended and cannot anticipate the instant invention as now claimed. Withdrawal of this rejection is respectfully requested.

III. Rejection of Claims Under 35 U.S.C. 103(a)

Claims 45, 46 and 48-55 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Cance et al. (US Patent 6,015,893), in view of Baracchini et al. (US Patent 5,801,154). The Examiner suggests that it would have been *prima facie* obvious to one of ordinary skill to modify the method of Cance et al. To

administer modified antisense as claimed as taught by Baracchini et al. because such modifications were routine and well known in the art and because Cance et al. explicitly teach incorporating such modifications into antisense. The Examiner suggests one of skill would have been motivated to incorporate the modifications because such modifications were known to enhance stability and improve success. The Examiner suggests that an expectation of success is provided by the method of Cance and the knowledge that using modification is routine. Applicants respectfully traverse this rejection.

As discussed *supra*, Cance et al. disclose the use of antisense compounds targeted to the coding region of human focal adhesion kinase and their use *ex vivo* to inhibit tumor growth in mice. Although the patent mentions targeting other regions of the gene in general terms, nowhere does this patent teach or suggest which nucleobase regions to target within those general regions as now claimed.

The secondary reference cited fails to overcome the deficiencies in teaching of this primary reference.

Baracchini et al. disclose antisense compounds targeted to multi-drug resistance-associated protein. Although this patent

discloses in general terms modifications to antisense and regions to be targeted by antisense, nowhere does this patent teach or suggest antisense to any region of human focal adhesion kinase nor any nucleobase regions to target within general regions as now claimed.

To establish a *prima facie* case of obviousness, three basic criteria must be met. MPEP 2143. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art must teach or suggest all claim limitations. Clearly, the art as combined fails to teach or suggest the limitations of the claims as amended which recite specific nucleobase regions within each target region to be targeted by antisense compounds. It is only with the specification in hand that one of skill would understand how to use the methods of the instant invention and be aware of the successful use of these methods. Therefore, this combination of art fails to provide an expectation of success as well as failing to teach the limitations

of the claims as amended. Accordingly, withdrawal of this rejection is respectfully requested.

IV. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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